kidneys applied to reasonable costs. Certain long-standing arrangements that existed before March 3, 1988 (for example, an OPO that procures kidneys at a military transplant hospital for transplant at that hospital), will be deemed to be Medicare kidneys for cost reporting statistical purposes. The OPO must submit a request to the fiscal intermediary for review and approval of these arrangements.

[62 FR 43668, Aug. 15, 1997, as amended at 71 FR 31046, May 31, 2006]

§413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

(a) A transplant center's total costs for all organs is reduced by the costs associated with procuring organs sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. Organs are defined in §486.302 (only covered organs will be paid for on a reasonable cost basis).

(b) Transplant center hospitals must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare fiscal intermediaries.

(c) Medicare costs are based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total number of usable organs applied to reasonable costs.

§413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.

Except as noted in §413.174(f), items and services furnished on or after January 1, 2011, under section 1881(b)(14)(A) of the Act and as identified in §413.217 of this part, are paid under the ESRD prospective payment system described in §413.215 through §413.235 of this part.

(a) *Qualifications for payment.* To qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter.

(b) *Payment for items and services.* CMS will not pay any entity or supplier other than the ESRD facility for covered items and services furnished to a Medicare beneficiary. The ESRD facility must furnish all covered items and services defined in §413.217 of this part either directly or under arrangements.

[75 FR 49199, Aug. 12, 2010]

§413.215 Basis of payment.

(a) Except as otherwise provided under §413.235 or §413.174(f) of this part, effective January 1, 2011, ESRD facilities receive a predetermined per treatment payment amount described in §413.230 of this part, for renal dialysis services, specified under section 1881(b)(14) of the Act and as defined in §413.217 of this part, furnished to Medicare Part B fee-for-service beneficiaries.

(b) In addition to the per-treatment payment amount, as described in §413.215(a) of this part, the ESRD facility may receive payment for bad debts of Medicare beneficiaries as specified in §413.178 of this part.

[75 FR 49200, Aug. 12, 2010]

§413.217 Items and services included in the ESRD prospective payment system.

The following items and services are included in the ESRD prospective payment system effective January 1, 2011:

(a) Renal dialysis services as defined in §413.171; and

(b) Home dialysis services, support, and equipment as identified in §410.52 of this chapter.

[75 FR 49200, Aug. 12, 2010]

§413.220 Methodology for calculating the per-treatment base rate under the ESRD prospective payment system effective January 1, 2011.

(a) *Data sources.* The methodology for determining the per treatment base rate under the ESRD prospective payment system utilized:

(1) Medicare data available to estimate the average cost and payments for renal dialysis services.

(2) ESRD facility cost report data capturing the average cost per treatment.

(3) The lowest per patient utilization calendar year as identified from Medicare claims is calendar year 2007.

(4) Wage index values used to adjust for geographic wage levels described in § 413.231 of this part.

(5) An adjustment factor to account for the most recent estimate of increases in the prices of an appropriate market basket of goods and services provided by ESRD facilities.

(b) *Determining the per treatment base rate for calendar year 2011.* Except as noted in § 413.174(f), the ESRD prospective payment system combines payments for the composite rate items and services as defined in § 413.171 of this part and the items and services that, prior to January 1, 2011, were separately billable items and services, as defined in § 413.171 of this part, into a single per treatment base rate developed from 2007 claims data. The steps to calculating the per-treatment base rate for 2011 are as follows:

(1) *Per patient utilization in CY 2007, 2008, or 2009.* CMS removes the effects of enrollment and price growth from total expenditures for 2007, 2008 or 2009 to determine the year with the lowest per patient utilization.

(2) *Update of per treatment base rate to 2011.* CMS updates the per-treatment base rate under the ESRD prospective payment system in order to reflect estimated per treatment costs in 2011.

(3) *Standardization.* CMS applies a reduction factor to the per treatment base rate to reflect estimated increases resulting from the facility-level and patient-level adjustments applicable to the case as described in § 413.231 through § 413.235 of this part.

(4) *Outlier percentage.* CMS reduces the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD prospective payment system that are outlier payments as described in § 413.237 of this part.

(5) *Budget neutrality.* CMS adjusts the per treatment base rate so that the aggregate payments in 2011 are estimated to be 98 percent of the amount that would have been made under title XVIII of the Social Security Act if the ESRD prospective payment system described in section 1881(b)(14) of the Act were not implemented.

(6) *First 4 Years of the ESRD prospective payment system.* During the first 4 years of ESRD prospective payment system (January 1, 2011 to December 31, 2013), CMS adjusts the per-treatment base rate in accordance with § 413.239(d).

[75 FR 49200, Aug. 12, 2010]

§ 413.230 Determining the per treatment payment amount.

The per-treatment payment amount is the sum of:

(a) The per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in §§ 413.232 and 413.235 of this part;

(b) Any outlier payment under § 413.237; and

(c) Any training adjustment add-on under § 414.335(b).

[75 FR 49200, Aug. 12, 2010]

§ 413.231 Adjustment for wages.

(a) CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located.

(b) The application of the wage index is made on the basis of the location of the ESRD facility in an urban or rural area as defined in this paragraph (b).

(1) *Urban area* means a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB.

(2) *Rural area* means any area outside an urban area.

[75 FR 49200, Aug. 12, 2010]

§ 413.232 Low-volume adjustment.

(a) CMS adjusts the base rate for low-volume ESRD facilities, as defined in paragraph (b) of this section.

(b) Definition of low-volume facility. A low-volume facility is an ESRD facility that:

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports,